REMARKS

Reconsideration and allowance are respectfully requested. The amendments are fully supported by the original disclosure and, thus, no new matter is added. In particular, the amendment of claims 17 and 25 is supported by page 3, lines 20-21, and page 4, lines 16, of the present specification.

Claims 17-47 are pending. Non-elected claims 19-24, 27, 29-33, 38, 41, 44 and 47 were withdrawn from consideration by the Examiner. Applicants request rejoinder of the non-elected claims upon an indication that an elected claim is allowable.

Information Disclosure Statement

Applicants request consideration of the Information Disclosure Statement filed April 16, 2009. The relevance of foreign patent document JP 53-127896 to the original claims is indicated in the search and preliminary examination reports for related Int'l Appln. No. PCT/NL03/00352. Further, US 4,181,742 appears to be an English language counterpart of JP 53-127896.

To satisfy their continuing duties of candor and good faith, Applicants bring to the attention of the Examiner related subject matter in Appln. Nos. 10/450,022, 10/450,185, and 11/976,575. The Examiner is invited to consider their prosecution histories and the prior art of record in those applications, which are accessible through the PTO's Image File Wrapper (IFW), in view of the Federal Circuit's holding in *McKesson Information Solutions v. Bridge Medical*, 82 USPQ2d 1865 (Fed. Cir. 2007). To avoid duplication of those materials in the PTO's records, reference to the IFW is encouraged but Applicants would be ready to submit copies of these materials if the Examiner prefers.

Specification/Claim Objections

The specification was objected to by the Examiner. The hyperlink is deleted. Therefore, withdrawal of the objection is requested.

35 U.S.C. 102 – Novelty

A claim is anticipated only if each and every limitation as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is claimed. See *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

As an initial matter, Applicants emphasize that the terms "enzyme" and "hydrolysate" cannot be used interchangeably. Enzymes are polypeptides that catalyze (i.e., increase the rates of) chemical reactions. A hydrolysate is a solution of amino acids and peptides prepared from polypeptides (i.e., proteins and peptides) by acid or enzymatic hydrolysis. The hydrolysate may be used, for example, as a high-protein dietary supplement. Enzymes in the hydrolysate are inactivated before its use in foods or beverages (see, for example, Edens '791 as discussed in more detail below).

Claims 17-19, 25-26, 28, 34-37, 39-40, 42-43 and 45-46 were rejected under Section 102(b) as allegedly anticipated by Nagodawithana et al. (eds., *Enzymes in Food Processing, 3rd Ed.*, Academic Press, Chapter 16, pp. 448-449, 1993). But Applicants traverse because their claims require that (1) the prolyl-specific endoprotease cuts a protein or peptide at places where the protein or peptide contains a prolyl residue and (2) the auxiliary enzyme is a protease.

By contrast, Nagodawithana discloses that haze in beer results from interactions between proteins and polyphenolic procyanidins. Bromelin, papain, and pepsin are the proteases disclosed by Nagodawithana. These proteases are not prolyl-specific endoproteases that cut a protein or peptide at places where the protein or peptide contains a prolyl residue. Thus, the cited document does not teach Applicants' claimed method for the prevention or reduction of haze in a beverage. Therefore, claims 17 and 25 (as well as claims dependent thereon) are not anticipated by Nagodawithana.

Claims 17, 19, 25, 28, 34, 39, 42 and 45 were rejected under Section 102(b) as allegedly anticipated by Shetty et al. (US 4,532,213). But Applicants traverse because their claims require that (1) the prolyl-specific endoprotease cuts a protein or peptide at

places where the protein or peptide contains a prolyl residue and (2) the auxiliary enzyme is a protease.

It was alleged in the Office Action that Shetty teaches adding the fungus A. niger comprising a proline-specific endoprotease and an auxiliary enzyme to an aqueous medium. This is incorrect. Shetty merely refers to an acid fungal protease. No endoprotease is ever mentioned in Shetty, much less a prolyl-specific endoprotease. Example 1 of Shetty discloses how to grow A. niger in an aqueous nutrient medium. The skilled person reading Shetty, however, would not have considered adding A. niger to a beverage and using it as such because only enzymes isolated or secreted from the whole cells would interact with proteins in the beverage.

Moreover, Shetty discloses co-producing an acid fungal protease and glucoamylase, and thereafter separating a solid phase containing acid fungal protease and a liquid phase containing glucoamylase (col. 2, ll. 14-18). Shetty discloses that acid fungal protease is potentially useful in the food and brewing industries (col. 1, ll. 10-15). Thus, Shetty teaches separating acid fungal protease and glucoamylase produced by A. niger, then using the separated acid fungal protease only. This teaches away from using both the acid fungal protease and glucoamylase as in Applicants' claimed invention.

Even if both enzymes were used in combination, the acid fungal protease and glucoamylase described in Shetty would only cut a polypeptide at one type of site: a specific amino acid sequence recognized by the acid fungal protease (col. 2, line 14-18). An amylase is an enzyme that breaks down starch (i.e., a polymerized sugar) into its component oligosaccharides. This is completely different from the auxiliary proteolytic enzyme required by Applicants' claimed invention that hydrolyzes peptide bonds in the protein.

Finally, the independent claims have their own distinct requirements. The two proteases required therein cut a polypeptide chain in two different ways. This cutting in two different places results in further prevention or reduction of haze than is achievable with a prolyl-specific endoprotease alone. The use of only one protease as disclosed by Shetty does not have this advantage. More particularly, claim 25 requires that addition of the auxiliary proteolytic enzyme results in further prevention or reduction of haze in

the beverage than is achievable with the prolyl-specific endoprotease alone. Shetty fails to add either a prolyl-specific endoprotease or an auxiliary proteolytic enzyme.

Thus, the cited document neither teaches nor makes obvious Applicants' claimed method for the prevention or reduction of haze in a beverage. Therefore, claims 17 and 25 (as well as claims dependent thereon) are not anticipated by Shetty.

Claims 17-20, 25-26, 28, 34-37, 39-40, 42-43 and 45-46 were rejected under Section 102(a) or 102(e) as allegedly anticipated by Edens et al. (US 2004/0241791). But Applicants traverse because their claims require that (1) the prolyl-specific endoprotease cuts a protein or peptide at places where the protein or peptide contains a prolyl residue and (2) the auxiliary enzyme is a protease.

Edens '791 clearly describes in its examples that the hydrolysates are inactivated before use. See:

> EXAMPLE 1 [0210] "Hydrolysis of Beta Casein using . . . in combination with a proline specific endoprotease . . . the reaction [i.e., hydrolysis] was stopped by heating the solution for 15 minutes at 90°C."
> EXAMPLE 2 [0215]: "Following heat inactivation of . . . to give final casein concentrations the hydrolysate obtained . . ."
> EXAMPLE 5 [0250] "The incubation was stopped by keeping the material for 10 minutes at 100°C."
> EXAMPLE 7 [0275] "At the end the solution was kept at 95°C for 5 minutes to inactivate the enzyme and to pasteurize the solution."
> EXAMPLE 8 [0279] "At the end the solution was kept at 95°C for 5 minutes to inactivate the enzyme and to pasteurize the solution."

Edens '791 [0039] provides "an enzyme mixture . . . . to produce a protein hydrolysate." It is also clearly indicated in [0045] that the enzyme mixture is particularly suitable for use in the production of hydrolysates intended for flavoring and nutrient enhancement of sport drinks and juice-based beverages.

Edens '791 [0047] also discloses the use of 5-10% (w/v) protein hydrolysate in food. From its Examples, it is clear that the enzymes, which are used to produce the hydrolysate, are inactivated before addition to a beverage (see above citations). The hydrolysate that would be produced in accordance with the disclosure of Edens '791 does not contain active enzymes because any enzymes were inactivated prior to addition to the beverage. An inactivated proteolytic enzyme in the hydrolysate, when added

to a beverage, will not prevent or reduce haze therein because proteins and peptides in the beverage would not be hydrolyzed. The lack of enzymatic activity in the hydrolysate of Edens '791 fails to satisfy the requirement for adding a prolyl-specific endoprotease and an auxiliary proteolytic enzyme to a beverage.

Thus, the cited document neither teaches nor makes obvious Applicants' claimed method for the prevention or reduction of haze in a beverage. Therefore, claims 17 and 25 (as well as claims dependent thereon) are not anticipated by Edens '791.

Withdrawal of the Section 102 rejections is requested because the cited documents fails to disclose all limitations of the claimed invention.

35 U.S.C. 103 – Nonobviousness

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See id. ("Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue"). The use of hindsight reasoning is impermissible. See id. at 1397 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning"). Thus, a prima facie case under Section 103(a) requires "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." *Kahn* at 1335; see *KSR* at 1396. An inquiry is required as to "whether the improvement is more than the predictable use of prior art elements according to their established functions." Id. at 1396. But a claim that is directed to a combination of prior art elements "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." Id.

Finally, a determination of prima facie obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 21-22 were rejected under Section 103(a) as allegedly unpatentable over Nagodawithana et al. (eds., *Enzymes in Food Processing, 3rd Ed.*, Academic Press, Chapter 16, pp. 448-449, 1993) in view of Edens et al. (US 6,372,282). Applicants traverse.

Nagodawithana was discussed above. Edens '282 discloses preparing a protein hydrolysate with a mixture of proteolytic enzymes comprising a single exopeptidase in combination with one or more endoproteases (col. 2, ll. 5-8 and ll. 46-48). Such hydrolysates may be used to prepare a hydrolysate that may be used in food applications (col. 2, ll. 48-50). As in Edens '791, the product (i.e., hydrolysate) is used in a beverage instead of the active ingredient (i.e., enzyme mixture).

Although not specifically mentioned in Edens '282, it is common in the art that the enzymes are inactivated at the end of producing the hydrolysate and before adding the hydrolysate to another medium (see Edens '791). Thus, by analogy to the preceding discussion of Edens '791, adding the hydrolysate of Edens '282 to a beverage does not produce the effect (i.e., preventing or reducing haze) required by Applicants' claimed methods. Both Edens documents teach using the resultant product (i.e., a hydrolysate comprising inactivated enzymes) whereas Applicants teach the use of active proteases for prevention or reduction of haze in a beverage. Without the active ingredients (i.e., proteases), the effect required by Applicants claims 17 and 25 would not be obtained because the proteins and peptides in the beverage would not be hydrolyzed.

The failure of Nagodawithana to disclose the claimed invention is not remedied by the attempt to combine that disclosure with Edens '282 because they do not render obvious Applicants' invention as represented by independent claim 17. Therefore, claims 21-22 which depend from independent claim 17 are also not rendered obvious by the cited documents because all limitations of the independent claim are incorporated in its dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Withdrawal of the Section 103 rejection is requested because the claims would not have been obvious to one of ordinary skill in the art when this invention was made.

Double Patenting

Although claims 17-18, 25-26, 28, 34-37, 39-40, 42-43 and 45-46 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-16, 31, 43 and 45-61 of copending Application No. 10/450,022, Applicants traverse because after an indication of allowable subject matter, they may submit a terminal disclaimer, cancel conflicting claims, or amend the claims.

Although claims 17-20, 25-26, 28, 34-37, 39-40, 42-43 and 45-46 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 14-17 of copending Application No. 10/433,747, Applicants traverse because after an indication of allowable subject matter, they may submit a terminal disclaimer, cancel conflicting claims, or amend the claims.

Conclusion

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if additional information is required.

Respectfully submitted,

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